

### **DETAILED ACTION**

Applicants' response, which included cancellation of claims 21-44 and amendment to claims 1-19, filed on 12/30/2010, is made of record. Claims 1-20 and 45 are now pending. In view of applicants' response, 112 first and second paragraph rejections made in the previous office action have been obviated. In addition, the 102/103 rejections over Shaper, 102 rejection over Obata, 102 rejection over Lee and 102/103 rejections over Sekiguchi have been obviated. However, new grounds of rejections are applied to currently pending claims.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 11, 12, 20 and 45 rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al. WO 2002/030891, equivalent US 6,849,622 used for English version.

Yasuda teaches compound of general formula I for treating rheumatoid arthritis, which includes instant genus of compounds. See formula I and note with the given definition of various variable groups, compounds taught by Yasuda include instant compounds. See column 2-20 for details of the invention, preferred embodiments and process of making. See column 20-220 for various examples of compounds made including Table 1-1d, Table 2-8 including compounds 1a-20, 1a-27, 1a-28, 1a-30 to 1a-41, 1a-64 to 1a-67, 1a-72, 1a-77 and 1a-87. Especially, see compound 1a-27.

Claims 1, 3-5, 11, 12, 20 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al., US 7,101,878.

Anderson teaches compound of general formula I for treating reproductive disorders and steroid hormone-dependent tumor such as prostate cancer, which includes instant genus of compounds. See formula I and note with the given definition of R<sup>8</sup> and other variable groups, compounds taught by Anderson include instant compounds. See column 3-6 for preferred embodiments. See entire document for details of the invention, process of making and compounds made. Especially, see compounds 73, 174 and 178 for pyrimidine compounds.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5, 11, 12, 20 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., US 7,101,878.

Anderson teaches compound of general formula I for treating reproductive disorders and steroid hormone-dependent tumor such as prostate cancer, which includes instant genus of compounds. See formula I and note with the given definition of  $R^8$  and other variable groups, compounds taught by Anderson include instant compounds. See column 3-6 for preferred embodiments. See entire document for details of the invention, process of making and compounds made. Especially, see compounds 11, 73, 92-94 152, 174, 178 and 465 for pyrimidine compounds.

Anderson does not exemplify all compounds generically embraced in compound of formula I especially those bearing pyrimidine core in the side chain of  $R^8$  group. However, Anderson exemplifies large number of compounds (over 835 compounds) including compounds 11, 71, 73, 92-94, 152, 174 and 178, 465, 473, 481, 492 as well as related compounds 91, 111 and 138 and thereby provides guidance and motivation to make the genus of compound of formula I. Hence, one trained in the art would be

motivated to make the compounds of the genus of formula I and expect them to have the use taught therein.

In addition, Anderson exemplifies compounds 11, 71, 92-94, 152, 465, 473, 481 and 492.

While said compounds doesn't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. side chain bearing cycloalkylalkylamino in 2-position of the pyrimidine in Anderson versus and side bearing cycloalkylalkylamino in 4- position of the pyrimidine in the claimed invention. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1, 3-5, 11, 12, 20 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo et al., WO 2003035638, equivalent US 7,473,695 used for English version.

Kubo teaches compound of general formula I for treating inflammatory disorder such as rheumatoid arthritis, which includes instant genus of compounds. See formula I and note with the given definition of various variable groups, compounds taught by Kubo include instant compounds. See column 2-37 for details of the invention, preferred

embodiments and process of making. See column 37-122 for various examples of compounds made including examples 18-25, 128-141, 186-197, 270, 454-460, 545-552, and Table 72, 73, 74, 75. Especially, see compounds 383-386 for pyrimidine compounds.

Kubo does not exemplify all compounds generically embraced in compound of formula I especially those bearing pyrimidine core in the side chain of R<sup>8</sup> group. However, Kubo exemplifies large number of compounds including compounds 18-25, 128-141, 186-197, 270, 454-460, 545-552, and Table 72, 73, 74, 75 and thereby provides guidance and motivation to make the genus of compound of formula I. Hence, one trained in the art would be motivated to make the compounds of the genus of formula I and expect them to have the use taught therein.

In addition, Kubo exemplifies compounds 383-386.

While said compounds don't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. side chain bearing cycloalkylalkylamino in 2-position of the pyrimidine in Kubo versus and side bearing cycloalkylalkylamino in 4- position of the pyrimidine in the claimed invention. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1, 3-5, 11, 12, 20 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al., WO 2002030891, equivalent US 6,849,622 used for English version.

Yasuda teaches compound of general formula I for treating inflammatory disorder such as rheumatoid arthritis, which includes instant genus of compounds. See formula I and note with the given definition of various variable groups, compounds taught by Yasuda include instant compounds. See column 2-20 for details of the invention, preferred embodiments and process of making. See column 20-220 for various examples of compounds made including Table 1-1d, Table 2-8 including compounds 1a-20, 1a-27, 1a-28, 1a-30 to 1a-41, 1a-64 to 1a-67, 1a-72, 1a-77 and 1a-87. Especially, see compounds 1a-20 and 1a-27.

Yasuda does not exemplify all compounds generically embraced in compound of formula I especially those bearing pyrimidine core. However, Yasuda exemplifies large number of compounds including compounds 11a-20, 1a-27, 1a-28, 1a-30 to 1a-41, 1a-64 to 1a-67, 1a-72, 1a-77 and 1a-87 and thereby provides guidance and motivation to make the genus of compound of formula I. Hence, one trained in the art would be motivated to make the compounds of the genus of formula I and expect them to have the use taught therein.

In addition, Yasuda exemplifies compound 1a-20.

While said compound doesn't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. side chain bearing cycloalkylalkylamino in 2-position of the pyrimidine in Yasuda versus and side bearing cycloalkylalkylamino in 4- position of the pyrimidine in the claimed invention. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1, 3-5, 11, 12, 20 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilhauer WO 2002/030891, equivalent US 6,432,469 used for English version.

Vilhauer teaches compound of general formula I for treating inflammatory disorder such as rheumatoid arthritis, which includes instant genus of compounds. See formula I and note when R<sub>1</sub> is mono or disubstituted pyrimidine with the given definition of other variable groups, compounds taught by Vilhauer include instant compounds. See column 2-11 for details of the invention, preferred embodiments and process of making. See column 22-27 for various examples of compounds made. Especially, see compound O.

While said compound doesn't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. side chain bearing cycloalkylalkylamino in 2-position of the pyrimidine in Vilhauer versus and side bearing cycloalkylalkylamino in 4- position of the pyrimidine in the claimed invention. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.



Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 57, 63, 64, 68, 72, 80, 81, 86, 87, 91, 92, 95, 96 and 10 of copending Application No. 10/812,075. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of compounds and composition embraced in the instant claims are obvious variant of the claimed species claims 57, 63, 64, 68, 72, 80, 81, 86, 87, 91, 92, 95, 96 and 10 of copending Application No. 10/812,075. While said compounds don't anticipate the scope of claimed invention, they are very closely related, being positional isomers of compounds i.e. the chain L-Y-R<sub>1</sub> in 2-position of the pyrimidine in the copending application versus and side bearing L-Y-R<sub>1</sub> in 4- position of the pyrimidine in the claimed invention. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above. Hence, it would be obvious to one trained in the art to make the compounds of the species claims of the

copending application including compounds embraced in the instant invention and expect them to have the use taught therein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

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Primary Examiner, Art Unit 1624